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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,191	07/30/2003	Richard D. Paoletti	DE-1495	9822
1109	7590	11/29/2005	EXAMINER	
ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK, NY 10020-1182			HUYNH, LOUIS K	
			ART UNIT	PAPER NUMBER
			3721	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/632,191	PAOLETTI, RICHARD D.
<b>Examiner</b>	<b>Art Unit</b>	
Louis K. Huynh	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 30 July 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-24 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-24 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 30 July 2003 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date .  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_ .

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 14-24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 14-19, 23 and 24 are directed to a safety seal method and thus do not further structurally limit the claimed article of previous claims. Claims 20-22 are objected to for being directed to a safety seal system and thus do not further structurally limit the claimed method of previous claims.
2. For purpose of examination, claims 14-24 are presumed to directly or indirectly depend on the method claim 13. Affirmation of this presumption is respectfully requested.

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "11". Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4: "said seal" lacks proper antecedent basis.

Claim 6, lines 1-2: "said warning statement includes visual cues and tactile awareness" lacks proper antecedent basis in the specification. Applicant is respectfully requested to point out where in the specification that teaches such claimed limitation.

Claim 11, line 1: "said seal has no lip" lacks proper antecedent basis. It is unclear as to what lip applicant is referring since the seal has no lip.

Claim 11, line 2: "the lip of the medicine container" lacks proper antecedent basis.

Claim 12, lines 1-2: "said pull tab cannot be felt until the seal is removed" is confusing because the pull tab is for tearing the perforated lines; therefore it must be felt in order to remove the seal.

Claim 13 appears to be incomplete because it does not set forth any step of applying heat to shrink the heat-shrink plastic cover to the medicine container, thus amounting a gap between the steps.

Claim 13, line 8: "said seal" lacks proper antecedent basis.

Claim 23, line 2: "the seal has no lip" lacks proper antecedent basis. It is unclear as to what lip applicant is referring since the seal has no lip.

Claim 23, lines 2-3: "the lip of the medicine container" lacks proper antecedent basis.

Claim 24, line 2: "the pull tab" lacks proper antecedent basis.

Claim 24, lines 2-3: "the pull tab cannot be felt until the seal is removed" is confusing because the pull tab is for tearing the perforated lines; therefore it must be felt in order to remove the seal.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Key (US 6,385,878).

With respect to claim 1, Key discloses a safety seal comprising a heat-shrink plastic cover (100) that is adapted to be placed over a medicine container (130), wherein the heat-shrink plastic cover is provided with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container.

With respect to claim 13, Key discloses a safety seal method including the steps of: placing a heat-shrink plastic cover (100) over a medicine container (130), and providing the heat-shrink plastic cover (100) with a written indicia (114) such as product name, ingredient or

directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container.

With respect to claims 2 and 14, the heat-shrink plastic cover (100) is provided with a set of perforated line (116) (FIG. 3).

With respect to claims 3 and 15, Key teaches in another embodiment that the heat-shrink plastic cover (100) is provided with a set of perforated lines (704a, 704b) that are configured as a pull tab (FIG. 7).

With respect to claims 4 and 16, Key teaches in another embodiment that the heat-shrink plastic cover (100) is provided with a set of perforated lines (604a, 604b) that are configured as a tear strip (FIG. 6).

With respect to claims 5 and 17, the written indicia (114) can include product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container prior to removing the heat-shrink plastic cover (100).

With respect to claims 6 and 18, the heat-shrink plastic cover (100) includes visual cues such as the written indicia (114) and tactile awareness such as the texture of the heat-shrink plastic cover and/or the edge of the heat-shrink plastic cover disposed on top of the medicine container closure.

With respect to claims 7, 8, 19 and 21, the container (130) is a vial and is configured as a bottle shaped container.

With respect to claims 11 and 23, the heat-shrink plastic cover (100) covers the medicine container's mouth as shown in FIGS. 3, 6, and 7.

With respect to claims 12 and 24, the texture of the heat-shrink plastic cover and/or the edge of the heat-shrink plastic cover would provide a tactile awareness of the heat-shrink plastic cover being in place.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Key (US 6,385,878).

The method and the heat-shrink plastic cover of Key meets all of applicants claimed subject matter but lack the specific teaching of the medicine container being configured as an intravenous bag. However, intravenous is a solution to be administered in to living body and thus the intravenous bag having outlet port that must be labeled with written indicia and must be protected from tampering; therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have modified the method of Key by having placed the heat-shrink plastic cover over an intravenous bag having outlet port, as required, so that the user can be informed of the integrity of the intravenous bag prior to usage.

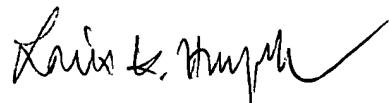
10. Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Key (US 6,385,878) in view of Novice et al. (US 5,205,827).

The method and the heat-shrink plastic cover of Key meets all of applicants claimed subject matter but lack the specific teaching of the medicine container being configured as a syringe. However, Novacek teaches that medical syringe must be protected in a sterile condition such as wrapping the syringe with heat-shrink plastic cover (308) that serve as a tamperproof (FIG. 55) and assist in maintaining the sterility of the syringe (col. 28, line 56 – col. 29, line 8). Therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have modified the method of Key by having placed the heat-shrink plastic cover over a syringe, as taught by Novacek, in order to provide tamperproof and to assist in maintaining the sterility of the syringe.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure has been cited on form PTO-892 along with the applied references.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is 571-272-4462. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.
13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Louis K. Huynh  
Primary Examiner  
Art Unit 3721

November 25, 2005